

AMENDED IN SENATE MARCH 29, 2012

SENATE BILL

No. 1329

Introduced by Senator Simitian

February 23, 2012

An act to amend Sections 150201, 150202, 150204, and 150205 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 1329, as amended, Simitian. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish, by ordinance, a repository and distribution program under which a pharmacy that is owned by or contracts with the county may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Existing law requires a county that has established a program to establish procedures to, among other things, ensure proper safety and management of any medications collected and maintained by a participating pharmacy. Existing law authorizes a skilled nursing facility, specified drug manufacturer, or pharmacy wholesaler to donate medications to the program. Existing law requires medication under the program to be dispensed to an eligible patient, destroyed, or returned to a reverse distributor, as specified. Except in cases of noncompliance, bad faith, or gross negligence, existing law prohibits certain people and entities from being subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the program's provisions.

This bill would authorize a county to establish the program by action of the county board of supervisors or by action of a public health officer

of the county, as prescribed. This bill would *also* authorize a ~~primary care clinic dispensary, as defined, specified primary care clinics and pharmacies~~ to participate in the program. This bill would require a pharmacy or clinic seeking to participate in the program to inform the county health department in writing of its ~~intent, intent and prohibit the pharmacy or clinic from participating until and require~~ the county board of supervisors or public health officer to approve the pharmacy or clinic health department has confirmed that it has received this notice. This bill would require participating pharmacies and clinics to disclose specified information to the county health department and require the county board of supervisors or public health officer to make this information available upon request to the California State Board of Pharmacy. This bill would authorize the county board of supervisors, public health officer, and California State Board of Pharmacy to prohibit a pharmacy or clinic from participating in the program, under certain circumstances. This bill would authorize licensed health and care facilities, as specified, to donate unused medications to the program. ~~This bill would authorize medication under the program to be transferred to another participating pharmacy or primary care clinic.~~ This bill would also make other conforming changes to those provisions.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 150201 of the Health and Safety Code
2 is amended to read:
3 150201. ~~(a) For purposes of this division, “medication”~~
4 150201. *For purposes of this division:*
5 (a) *“Eligible entity” means all of the following:*
6 (1) *A licensed pharmacy, as defined in subdivision (a) of Section*
7 *4037 of the Business and Professions Code, that is county owned*
8 *or that contracts with the county pursuant to this division.*
9 (2) *A licensed pharmacy, as defined in subdivision (a) of Section*
10 *4037 of the Business and Professions Code, that is owned and*
11 *operated by a licensed primary care clinic, as defined in Section*
12 *1204.*
13 (3) *A licensed primary care clinic, as defined in Section 1204,*
14 *that is licensed to administer and dispense drugs pursuant to*

1 *subparagraph (A) of paragraph (1) of subdivision (a) of Section*
2 *4180 of the Business and Professions Code.*

3 (b) “Medication” or “medications” means a dangerous drug,
4 as defined in Section 4022 of the Business and Professions Code.

5 ~~(b) For purposes of this division, “primary care clinic~~
6 ~~dispensary” means a licensed primary care clinic, as defined in~~
7 ~~Section 1204, that is licensed to administer and dispense drugs~~
8 ~~pursuant to subparagraph (A) of paragraph (1) of subdivision (a)~~
9 ~~of Section 4180 of the Business and Professions Code.~~

10 (c) “Participating entity” means an eligible entity that has
11 received written or electronic documentation from the county
12 health department pursuant to paragraph (3) of subdivision (a) of
13 Section 150204 and that operates a repository and distribution
14 program pursuant to this division.

15 SEC. 2. Section 150202 of the Health and Safety Code is
16 amended to read:

17 150202. Notwithstanding any other provision of law, the
18 following health and care facilities may donate unused medications
19 under a program established pursuant to this division:

20 (a) A licensed general acute care hospital, as defined in Section
21 1250.

22 (b) A licensed acute psychiatric hospital, as defined in Section
23 1250.

24 (c) A licensed skilled nursing facility, as defined in Section
25 1250, including a skilled nursing facility designated as an
26 institution for mental disease.

27 (d) A licensed intermediate care facility, as defined in Section
28 1250.

29 (e) A licensed intermediate care facility/developmentally
30 disabled-habilitative facility, as defined in Section 1250.

31 (f) A licensed intermediate care facility/developmentally
32 disabled-nursing facility, as defined in Section 1250.

33 (g) A licensed correctional treatment center, as defined in
34 Section 1250.

35 (h) A licensed psychiatric health facility, as defined in Section
36 1250.2.

37 (i) A licensed chemical dependency recovery hospital, as defined
38 in Section 1250.3.

39 (j) A licensed residential care facility for the elderly, as defined
40 in Section 1569.2.

1 (k) A licensed residential care facility for persons with chronic,
2 life-threatening illness, as defined in Section 1568.01.

3 (l) *An approved mental health rehabilitation center, as described*
4 *in Section 5675 of the Welfare and Institutions Code.*

5 SEC. 3. Section 150204 of the Health and Safety Code is
6 amended to read:

7 150204. (a) (1) A county may establish, by an action of the
8 county board of supervisors or by an action of the public health
9 officer of the county, as delegated by the county board of
10 supervisors, a repository and distribution program for purposes of
11 this division.

12 (2) ~~Only a pharmacy that is county-owned or that contracts with~~
13 ~~the county pursuant to this division, or a primary care clinic~~
14 ~~dispensary, as defined in subdivision (b) of Section 150201, is an~~
15 *eligible entity, pursuant to subdivision (a) of Section 150201, may*
16 *participate in this program to dispense medication donated to the*
17 *drug repository and distribution program.*

18 (3) ~~An eligible pharmacy or primary care clinic dispensary entity~~
19 *that seeks to participate in the program shall inform the county*
20 *health department in writing of its intent to participate in the*
21 *program. An eligible pharmacy or primary care clinic dispensary*
22 *entity may not participate in the program unless it is approved by*
23 ~~the county board of supervisors or the public health officer of the~~
24 ~~county until it has received written or electronic documentation~~
25 ~~from the county health department confirming that the department~~
26 ~~has received its notice of intent.~~

27 (4) (A) ~~A participating pharmacy or primary care clinic~~
28 ~~dispensary entity shall disclose to the county health department~~
29 *the name and location of the source of all donated medication it*
30 *receives.*

31 (B) ~~A participating primary care clinic dispensary primary care~~
32 ~~clinic, as described in paragraph (3) of subdivision (a) of Section~~
33 ~~150201 shall disclose to the county health department the licensed~~
34 ~~physician to who shall be accountable to the California State Board~~
35 ~~of Pharmacy for the clinic's program operations pursuant to this~~
36 ~~division.~~

37 (C) The county board of supervisors or public health officer of
38 the county shall, upon request, make available to the *California*
39 *State Board of Pharmacy* the information in this paragraph.

1 (5) The county board of supervisors, the public health officer
2 of the county, and the *California* State Board of Pharmacy may
3 prohibit a ~~pharmacy or primary care clinic dispensary~~ *an eligible*
4 *or participating entity* from participating in the program if ~~the~~
5 ~~pharmacy or primary care clinic dispensary~~ *the entity* does not
6 comply with the provisions of the program, pursuant to this
7 division.

8 (b) A county that elects to establish a repository and distribution
9 program pursuant to this division shall establish procedures for,
10 at a minimum, all of the following:

11 (1) Establishing eligibility for medically indigent patients who
12 may participate in the program.

13 (2) Ensuring that patients eligible for the program shall not be
14 charged for any medications provided under the program.

15 (3) Developing a formulary of medications appropriate for the
16 repository and distribution program.

17 (4) Ensuring proper safety and management of any medications
18 collected by and maintained under the authority of a ~~county-owned~~
19 ~~or county-contracted, licensed pharmacy or primary care clinic~~
20 ~~dispensary~~ *participating entity*.

21 (5) Ensuring the privacy of individuals for whom the medication
22 was originally prescribed.

23 (c) Any medication donated to the repository and distribution
24 program shall comply with the requirements specified in this
25 division. Medication donated to the repository and distribution
26 program shall meet all of the following criteria:

27 (1) The medication shall not be a controlled substance.

28 (2) The medication shall not have been adulterated, misbranded,
29 or stored under conditions contrary to standards set by the United
30 States Pharmacopoeia (USP) or the product manufacturer.

31 (3) The medication shall not have been in the possession of a
32 patient or any individual member of the public, and in the case of
33 medications donated by a health or care facility, as described in
34 Section 150202, shall have been under the control of staff of the
35 health or care facility, as described in Section 150202.

36 (d) Only medication that is donated in unopened, tamper-evident
37 packaging or modified unit dose containers that meet USP
38 standards is eligible for donation to the repository and distribution
39 program, provided lot numbers and expiration dates are affixed.

1 Medication donated in opened containers shall not be dispensed
2 by the repository and distribution program.

3 (e) A pharmacist or physician shall use his or her professional
4 judgment in determining whether donated medication meets the
5 standards of this division before accepting or dispensing any
6 medication under the repository and distribution program.

7 (f) A pharmacist or physician shall adhere to standard pharmacy
8 practices, as required by state and federal law, when dispensing
9 all medications.

10 (g) Medication that is donated to the repository and distribution
11 program shall be handled in the following ways:

12 (1) Dispensed to an eligible patient.

13 (2) Destroyed.

14 (3) Returned to a reverse distributor.

15 (4) Transferred to another participating ~~pharmacy or primary~~
16 ~~care clinic dispensary~~ *entity* to be dispensed to eligible patients
17 pursuant to this division.

18 (h) Medication that is donated to the repository and distribution
19 program that does not meet the requirements of this division shall
20 not be distributed or transferred under this program and shall be
21 either destroyed or returned to a reverse distributor. This
22 medication shall not be sold, dispensed, or otherwise transferred
23 to any other entity.

24 (i) Medication donated to the repository and distribution program
25 shall be maintained in the donated packaging units until dispensed
26 to an eligible patient under this program, who presents a valid
27 prescription. When dispensed to an eligible patient under this
28 program, the medication shall be in a new and properly labeled
29 container, specific to the eligible patient and ensuring the privacy
30 of the individuals for whom the medication was initially dispensed.
31 Expired medication shall not be dispensed.

32 (j) Medication donated to the repository and distribution program
33 shall be segregated from the ~~pharmacy's or primary care clinic~~
34 ~~dispensary's~~ *participating entity's* other drug stock by physical
35 means, for purposes including, but not limited to, inventory,
36 accounting, and inspection.

37 (k) ~~The pharmacy or primary care clinic dispensary~~ A
38 *participating entity* shall keep complete records of the acquisition
39 and disposition of medication donated to, transferred, and dispensed
40 under the repository and distribution program. These records shall

1 be kept separate from the ~~pharmacy's or primary care clinic~~
2 ~~dispensary's~~ *participating entity's* other acquisition and disposition
3 records and shall conform to the Pharmacy Law (Chapter 9
4 (commencing with Section 4000) of Division 2 of the Business
5 and Professions Code), including being readily retrievable.

6 (l) Local and county protocols established pursuant to this
7 division shall conform to the Pharmacy Law regarding packaging,
8 transporting, storing, and dispensing all medications.

9 (m) County protocols established for packaging, transporting,
10 storing, and dispensing medications that require refrigeration,
11 including, but not limited to, any biological product as defined in
12 Section 351 of the Public Health and Service Act (42 U.S.C. Sec.
13 262), an intravenously injected drug, or an infused drug, shall
14 include specific procedures to ensure that these medications are
15 packaged, transported, stored, and dispensed at appropriate
16 temperatures and in accordance with USP standards and the
17 Pharmacy Law.

18 (n) Notwithstanding any other provision of law, a participating
19 ~~county-owned or county-contracted pharmacy or primary care~~
20 ~~clinic dispensary~~ *entity* shall follow the same procedural drug
21 pedigree requirements for donated drugs as it would follow for
22 drugs purchased from a wholesaler or directly from a drug
23 manufacturer.

24 SEC. 4. Section 150205 of the Health and Safety Code is
25 amended to read:

26 150205. The following persons and entities shall not be subject
27 to criminal or civil liability for injury caused when donating,
28 accepting, or dispensing prescription drugs in compliance with
29 this division:

30 (a) A prescription drug manufacturer, wholesaler, governmental
31 entity, ~~county-owned or county-contracted licensed pharmacy,~~ or
32 ~~primary care clinic dispensary~~ *participating entity*.

33 (b) A pharmacist or health care professional who accepts or
34 dispenses prescription drugs.

35 (c) A health or care facility, as described in Section 150202.